UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JOSEF BEER AND SHEILA BEER,	:	
Plaintiffs,	:	**Civil Action No.:**
v.	:	
EXACTECH, INC.;	:	
EXACTECH, U.S., INC.;	:	**COMPLAINT & DEMAND FOR JURY**
TPG, INC.; OSTEON HOLDINGS, INC.;	:	**TRIAL**
OSTEON MERGER SUB, INC.; and	:	
OSTEON INTERMEDIATE HOLDINGS II, INC.,	:	
Defendants.	:	

NOW COMES Plaintiffs JOSEF BEER ("Plaintiff") and SHEILA BEER (hereinafter collectively as "Plaintiffs"), by and through the undersigned attorneys, and bring this action against EXACTECH, INC. ("EXACTECH"), EXACTECH U.S., INC. ("EXACTECH US"), TPG, INC., OSTEON HOLDINGS, INC., OSTEON MERGER SUB, INC., and OSTEON INTERMEDIATE HOLDINGS II, INC (hereinafter collectively as "Defendants"), for personal injuries suffered as a proximate result of the implantation of the Optetrak Comprehensive Total Knee System (hereinafter referred to as the "Device" or "Devices") and allege as follows:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' developing, designing, testing, assembling, manufacturing, packaging, monitoring, labeling, preparing, distributing, marketing, supplying, storing, and/or selling of the Devices. The Devices as referred to in this Complaint include the Optetrak CC Polyethylene Tibial Inserts and the Optetrak Logic PSC Polyethylene Tibial Inserts.

2. Thousands of patients, like Plaintiff JOSEF BEER (hereafter individually referred to as "Plaintiff"), have been, and/or will be, required to undergo extensive revision surgery to remove and replace defective Devices due to a recent recall of these devices which first revealed to patients and surgeons that the polyethylene components within the prosthesis prematurely degrades over time causing an inflammatory response resulting in bone necrosis (death) also known as osteolysis. The recall notice admits that the recall and problems arose from failure to properly package the polyethylene insert component of the Device.

3. As a result of Defendants' failure to properly package the Device prior to distribution, the polyethylene liner prematurely degraded and Plaintiff required revision surgery due to severe pain, swelling, and instability in the knee and leg. These injuries were caused by early and preventable wear of the polyethylene insert and resulting component loosening and/or other failures causing serious complications including tissue damage, osteolysis, permanent bone loss and other injuries.

4. Recipients of the Device, like the Plaintiff, have been required to undergo revision surgeries well before the estimated life expectancy of a knee implant and at a much higher rate than should reasonably be expected for devices of this kind and have suffered pain and disability leading up to and after the revision surgery.

5. Despite knowledge that the Device was defective and resulted in premature failures and accompanying complications, Defendants only first issued a nationwide recall on February 7, 2022, advising the public that "most of our inserts since 2004 were packaged in out-of-specification . . . vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance."

6. As a direct and proximate result of the defective nature of Defendants' Devices

surgically implanted in Plaintiff which necessitated premature removal, Plaintiff JOSEF BEER suffered and will continue to suffer serious personal injuries, including pain, impaired mobility, rehabilitation, medical care, loss of enjoyment of life, and other medical and non-medical sequalae.

7. Plaintiffs bring this action for personal injuries suffered as a proximate result of failure of the Device. Plaintiffs accordingly seek compensatory and punitive damages, and all other available remedies provided to Plaintiffs under the law because of injuries JOSEF BEER sustained due to the Defendants' negligent, reckless, and wrongful conduct.

JURISDICTION & VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiffs and all Defendants.

9. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of New Jersey. At all relevant times, Defendants transacted, solicited, and conducted business in New Jersey through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in New Jersey. Furthermore, as set forth below, because TPG, its related entities, and Exactech served as agents, alter egos, and instrumentalities for each other, each entity's contacts are attributable to the other entities for purposes of establishing personal jurisdiction.

10. Venue is proper in this judicial district and division pursuant to 28 U.S.C. § 1391 because Plaintiffs are citizens and residents of Middlesex County, New Jersey.

THE PARTIES

11. Plaintiffs JOSEF BEER AND JODY REYNOLDS are residents and citizens of East Brunswick, New Jersey.

12. Defendant EXACTECH, INC. is a domestic, Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

13. Defendant EXACTECH, INC. develops, manufactures, packages, stores, distributes, markets, and sells orthopedic implant devices, including Optetrak Devices and related surgical instrumentation throughout the United States, including the State of New Jersey.

14. Defendant EXACTECH, INC. manufactured the Devices implanted in Plaintiff JOSEF BEER.

15. At all times relevant to this action, Defendant EXACTECH, INC. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device in interstate commerce and throughout the State of New Jersey and generated substantial revenue as a result.

16. Defendant EXACTECH U.S., INC., a wholly owned subsidiary of Defendant EXACTECH, INC., is a domestic Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

17. According to public filings, Defendant EXACTECH U.S., INC., conducts Defendants' U.S. sales and distribution activities.

18. EXACTECH U.S., INC. is engaged in the business of designing, developing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing Defendants' products, including Optetrak Devices, into commerce throughout the United States.

19. Upon information and belief, the Devices manufactured by Defendant EXACTECH, INC. were distributed by Defendant EXACTECH U.S., INC. throughout the United States, including to the Hospital for Special Surgery (HSS) in New York, New York and Stamford, Connecticut, where Plaintiff JOSEF BEER received his implants.

20. At all times relevant to this action, Defendant EXACTECH U.S., INC. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Device in interstate commerce and throughout the States of New York and generated substantial revenue as a result.

21. Defendant TPG, Inc. ("TPG"), also known as TPG Capital, is a Delaware corporation that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, TX 76102. TPG, Inc. is a citizen of Delaware and Texas.

22. TPG is a publicly traded company on the Nasdaq Stock Exchange with a business model based on privatizing companies.

23. TPG is a leading alternative asset manager that works with companies in many sectors, including the medical device sector.

24. The healthcare sector is one of TPG's most active sectors.

25. As set forth in further detail below, in February 2018, TPG paid over $737 million to merge with and acquire Exactech ("2018 Merger").

26. TPG is not a passive investor. It touts its ability to "create products and services [that have] delivered breakthrough innovation" in the healthcare industry, as well as its "unique approach" to "building great companies."

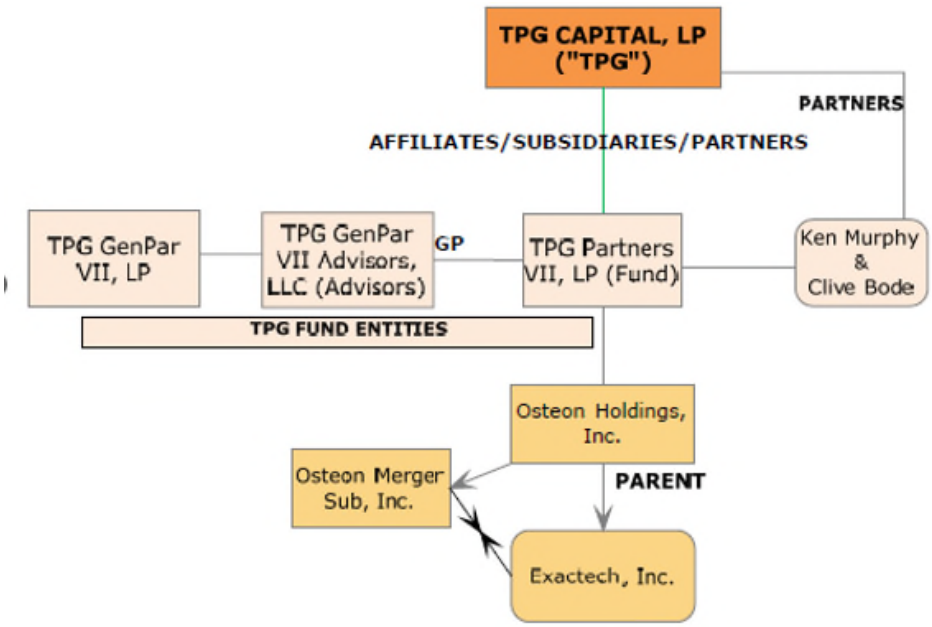
27. Defendant Osteon Holdings, Inc. is a Delaware corporation that has its principal place of business at 301 Commerce Street, Suite 300, Fort Worth, TX 76102, and is an indirect wholly owned subsidiary or indirect beneficially owned affiliate of TPG. Osteon Holdings, Inc. is a citizen of Delaware and Texas.

28. Defendant Osteon Merger Sub, Inc. is a Florida corporation that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, TX 76102, and is a wholly owned subsidiary of Osteon Holdings, Inc. Osteon Merger Sub, Inc. is a citizen of Florida and Texas.

29. Defendant Osteon Intermediate Holdings II, Inc., is a Delaware corporation that has its principal place of business at 2320 NW 66th Court, Gainesville, FL 32653 and has been identified in public court filings as the Parent corporation of Exactech, Inc. Osteon Intermediate Holdings II, Inc. is a citizen of Delaware and Florida.

30. Defendant Osteon Holdings, Inc. (formerly known as Osteon Holdings, LP), Defendant Osteon Merger Sub, Inc., and Defendant Osteon Intermediate Holdings II, Inc. (hereinafter "Osteon") are controlled by TPG.

31. The following chart demonstrates the relationships between these entities, as described in further detail below:



32. Defendant TPG, through and in concert with Osteon Holdings, Inc., Osteon Merger Sub, Inc., and Osteon Intermediate Holdings II, Inc. (collectively “TPG Defendants”) and other related entities, TPG Partners VII, L.P., TPG Genpar VII, LP, and TPG Genpar, VII Advisors,

LLC exercised control over the acquisition of Exactech and subsequent operations of Exactech for their direct benefit and they used Exactech to engage in improper conduct as outlined herein and caused harm to Plaintiff through such improper conduct.

33. TPG Defendants used Exactech as an agent, alter ego, and mere instrumentality such that TPG Defendants maintained control over Exactech. Moreover, Exactech and TPG Defendants should be held jointly and severally liable for each other's conduct.

LIST OF NON-PARTY INDIVIDUALS RELEVANT TO EXACTECH'S HISTORY, MERGER WITH TPG DEFENDANTS, AND PLAINTIFFS' CLAIMS

34. The following list provides information and background regarding non-party individuals referenced throughout this Complaint that are important to Exactech's history, merger with TPG Defendants, and Plaintiffs' claims against Defendants.

35. Dr. William "Bill" Petty is an orthopedic surgeon and was an original founder of Exactech. Dr. Petty served as Exactech's CEO from 1985 until 2014, after which he served as the Executive Chairman and Chairman of the Board of Exactech, Inc. prior to the 2018 merger. Following the 2018 Merger, Dr. William Petty held the same position and later became the Vice Chairman and a Director.

36. Betty Petty is the wife of Dr. William Petty and is an original founder of Exactech. She served in the dual capacities of Human Resources Coordinator and Director of Marketing Communications from the founding of Exactech until 2001. She was Vice President, Human Resources from February 2000 until May 2010. Ms. Petty also served as the Vice President, Administration and Secretary of Exactech, Inc prior to the 2018 Merger. Following the 2018 Merger, Betty Petty served as Secretary for one year and then Vice President, Administration for one year.

37. Gary J. Miller, Ph.D. is an original founder of Exactech. Dr. Miller is a biochemical engineer and served as an "innovation leader" since Exactech's inception. Dr. Miller served as Exactech's Executive Vice President, Research and Development prior to the 2018 Merger.

Following the 2018 Merger, Mr. Miller served in numerous capacities, and currently serves as the Executive Vice President of Research and Development Emeritus.

38. Mr. David W. Petty is the son of Dr. William Petty and Betty Petty. David Petty became Exactech's first employee in 1988. David Petty served as Exactech's Vice President of Operations from April 1991 until April 1993, Vice President of Marketing from 1993 until 2000, the Executive Vice President of Sales and Marketing from February 2000 until December 2007, President from 2007 until 2014, and the CEO from 2014 until January 2020, leading Exactech through the Merger with TPG Defendants. David Petty has been quoted as stating "[t]he secret sauce for Exactech has been the strong patient and people focused culture. . . ."[1]

39. In January 2020, Exactech announced that Dr. William Petty and his wife, Betty Petty would retire from the company. David Petty was transitioned from his role as Chief Executive Officer to Vice Chairman of the Exactech Board of Directors.

40. Joel C. Phillips has worked at Exactech since at least 1996 and served as Exactech's Executive Vice President, Chief Financial Officer, and Treasurer prior to 2018. Following the 2018 Merger, Mr. Phillips served for a certain number of years as Exactech's Chief Financial Officer and Treasurer.

41. Bruce Thompson has been at Exactech since 2004 and served as Exactech's Senior Vice President, Strategic Initiatives prior to the 2018 Merger. Following the 2018 Merger, Mr. Thompson served from 2019 to 2022 as the Senior Vice President, Strategic Initiatives and currently serves as the Senior Vice President, International Sales.

42. Donna Edwards has been at Exactech since 2001 and served as Exactech's Vice President, Legal and General Counsel prior to the 2018 Merger. Following the 2018 Merger, Ms. Edwards served in several roles. In 2019, she served as the Vice President, Legal and from 2020 to 2022, Ms. Edwards served as the Senior Vice President, Legal, Officer. Currently, Ms. Edwards serves as General Counsel and Senior Vice President, Legal.

[1] Press Release, Exactech, Exactech Announces Leadership Transition (Jan. 6, 2020), https://www.exac.com/exactech-announces-leadership-transition (last visited Jan. 9, 2023).

43. Christopher Roche was the Director of Engineering for Exactech Inc., prior to the 2018 Merger. Currently, Mr. Roche serves as Senior Vice President of Extremities at Exactech, Inc.

44. Steven Szabo was the Vice President of Marketing for Exactech, Inc., prior to the 2018 Merger.

45. Michael Mr. LaGatta is a full-time employee of TPG and many of its subsidiaries and affiliates. For example, Mr. LaGatta has signed agreements on behalf of a number of TPG entities, including, but not limited to:

a. TPG Global, LLC - Vice President

b. TPG Holdings, L.P. - Vice President

c. TPG Partner Holdings, L.P. - Vice President

d. TPG Group Advisors (Cayman), Inc. - Vice President

e. Osteon Holdings, L.P. ("Parent") - Vice President

f. Osteon Merger Sub, Inc. - Vice President

46. Jeffrey R. Binder is currently the Chairman and Chief Executive Officer of Exactech, Inc. Since 2015, he has served as a Senior Advisor to TPG Capital.

47. Daniel P. Hann has served as Exactech's Senior Vice President, Business Development since 2019. Mr. Hann has also served as a Senior Advisor to TPG Capital since at least 2017.

48. Kerem Bolukbasi served as Exactech's Chief Financial Officer and Treasurer from 2020 through August 2022, at which time he was relieved of his duties upon the advice and consent of TPG Capital Board Members. Prior to assuming his role as Chief Financial Officer and Treasurer of Exactech, Inc., Mr. Bolukbasi served as a TPG Employee including a private equity operations executive for TPG Capital, providing interim executive leadership and operational support of the management teams and board of directors for TPG portfolio companies. Mr. Bolukbasi also served as a TPG Advisor to Exactech.

49. Kendall Garrison serves on the nine-member Board of Directors of Exactech Inc. and is employed by TPG Capital. He joined TPG Capital in 2008 and currently serves as Principal of TPG Capital.

50. John Schilling serves on the nine-member Board of Directors of Exactech Inc. and is employed by TPG Capital. He joined TPG Capital in 2011 and currently serves as Partner, Head of Operations, TPG Capital.

51. Todd Sisitsky serves on the nine-member Board of Directors of Exactech Inc. and is employed by TPG Capital. He joined TPG Capital in 2003 and currently serves as President and Co-Managing Partner of TPG Capital.

52. Karen Golz is a member of the Exactech Board of Directors.

53. Darin Johnson joined Exactech and served as the Vice President of Marketing, Extremities from 2002 to 2016. In this role, he led Exactech's global teams of orthopedic surgeons, product managers, engineers, and sales professionals. In January 2020, Mr. Johnson became Exactech's President and Chief Executive Officer. While he continues to serve as Exactech's President, in March 2022, following the recalls discussed herein, Mr. Johnson was replaced as Chief Executive Officer by Jeffrey Binder.

FACTUAL BACKGROUND

54. Upon information and belief, the first Optetrak total knee system was available for implantation in 1994, building upon technology licensed from HSS.

55. At all times material hereto, Defendants designed, developed, tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold the Optetrak Comprehensive Total Knee System to hospitals in many states, including to the Hospital for Special Surgery in New York, New York.

56. Between 1994 and 2015, Defendants obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various Optetrak total knee system devices and components, including the OPTETRAK LOGIC® knee system and Optetrak Logic PSC Tibial Insert.

57. The Optetrak Total Knee System is classified as a knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. It features a mix of polyethylene and metal-based components.

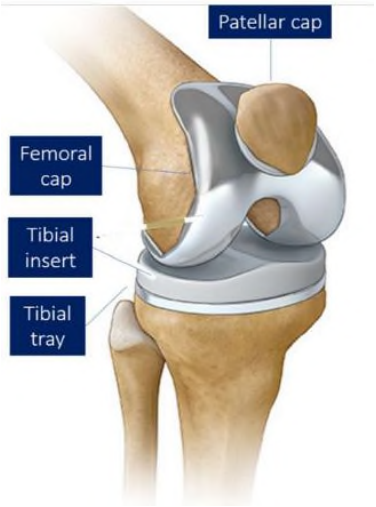
58. According to Defendants, the Optetrak Device introduced "novel implants and instruments to make the total knee procedure easier, faster, and more consistent, improving patient satisfaction for a more diverse population requiring total knee replacements."

59. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

60. 510(k) clearance only requires the manufacturer to notify the FDA under Section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device at least ninety days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

61. All the component parts comprising Plaintiff's Device were cleared for marketing by the FDA pursuant to 510(k) process or were marketed without receiving either 510(k) clearance or PMA approval by the FDA.

62. The Device is comprised of the following parts: a patellar cap, femoral cap, tibial insert and tibial tray, as shown below.



63. The patellar cap and tibial insert are made of polyethylene.

64. Defendants touted the Optetrak Device as being first-in-class in their product brochures.

65. In their marketing materials, the Defendants promised that the Device had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

66. Defendants promoted their Optetrak Devices as a system with nearly three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

67. However, Optetrak Devices have performed poorly when compared to their competitors. For example, the Australian Orthopaedic Association, a preeminent, internationally recognized orthopedic implant registry, has identified the Optetrak as an implant with a higher-than-expected rate of revision.

68. According to the 2020 Australian National Joint Replacement Registry, the rate of revision for a total knee replacement utilizing an Optetrak tibial component with a Optetrak-CR femoral component was 8.5% at ten years and 10.2% at ten years when implanted with a Optetrak-PS femoral component, which far exceeds international guidelines for accepted revision rates.

69. Per the recommendations established by the International Benchmarking Working Group and applied by the Australian Orthopaedic Association, the Optetrak Devices do not qualify for a "superiority benchmark" or even a "non-inferiority benchmark."

70. At all times relevant, Defendants have been aware of a high rate of early failures associated with the Optetrak Device.

71. Upon information and belief, by 2012, Defendants had further clinical evidence that

Optetrak Devices were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to "loose tibial component," "aseptic loosening," "pain and visible loosening," "polyethylene deformation," "polyethylene worn," and "pain, limited mobility, knee swelling and sensitivity" due to "loose" joint.

72. Upon information and belief, in 2013, complaints continued to be reported. Some examples include revision for "tibial loosening" just two years postoperatively, "revision due to tibial loosening," "during revision, the tibial component was found to be loose and easily removed," "revision of knee component due to loosening," and "revision due to pain and loosening."

73. Upon information and belief, the complaints of early onset failures continued in 2014. Some examples include "revision due to tibial loosening," "tibial loosening," "revision of optetrak knee components due to tibial loosening," "revision due to pain and loosening," "revision of optetrak knee components due to aseptic loosening," several reports described as "revision of knee components due to tibial loosening," and "revision of optetrak knee components reportedly due [to] aseptic loosening."

74. The general practice in orthopedic implant surgeries generally, and with Exactech implants specifically, is for the sale representative of the manufacturer, in this case Exactech's authorized representative and agent, hereinafter "the sales rep," to be present at the time of surgery to provide implant components to the surgeon, relieving the hospital of the responsibility for having on stock all potential sizes and components that may be needed in surgeries. This practice includes the original implant surgery and any revision surgery.

75. The sales reps of Exactech observed many instances of premature failures of the

Device with plain evidence upon revision of polyethylene debris that needed to get removed, a/k/a "debrided," visible bone loss or osteolysis and plainly loose components that were easy to remove due to lack of fixation. Often these sales reps would take the component from the surgeon to return to the company for inspection and analysis.

76. The sales reps of Exactech were under a duty to report these findings to the engineering and medical departments of Exactech who were under a duty to then do an investigation, analyze the removed component when available, also known as "retrieval analysis," and honestly and thoroughly report such findings to the FDA and the surgeons.

77. Despite Defendants' knowledge of early onset failures of the Optetrak Device, Defendants continued to manufacture, promote, and distribute the Device without alerting surgeons, patients, or the FDA of the potential increased risks of early onset failures of the Optetrak Device.

78. Defendants never changed the labeling, marketing materials, or product inserts to adequately and accurately warn patients or physicians of the associated increased risks of early failure due to loosening and/or polyethylene wear.

79. Not until August 30, 2021 did the Defendants take some action and issue a partial recall of all Optetrak All-polyethylene tibial components, including the OPTETRAK All-polyethylene CC Tibial Components; OPTETRAK All-polyethylene CR Tibial Components; OPTETRAK All-polyethylene CR Tibial Sloped Components; OPTERAK All-polyethylene PS Tibial Components; OPTETRAK HI-FLEX PS Polyethylene Tibial Components; OPTETRAK Logic All-polyethylene CR Tibial Components; OPTETRAK Logic All-polyethylene CRC Tibial Components; OPTETRAK Logic All-polyethylene PSC Tibial Components; OPTETRAK Logic Modular PS Tibial Components; OPTETRAK Logic RBK PS Tibial Components; TRULIANT

CR Tibial Inserts; TRULIANT CRC Tibial Inserts; TRULIANT PS Tibial Inserts; and TRULIANT PSC Tibial Inserts.

80. In issuing the August 2021 partial recall, Defendants stated that inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer. *See Class 2 Device Recall OPTETRAK Comprehensive Knee System*, FDA (Oct. 4, 2021), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266 (last visited Jan. 21, 2023).

81. According to the FDA website, "Exactech began notification to distributors and sales representatives on about 08/30/2021 via letter titled "URGENT MEDICAL DEVICE RECALL." Actions being taken by Exactech included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags. This will be performed in a phased approach over the next 12 months. Phase 1 includes immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2 includes, between 05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags." *Id.*

82. Despite initial communications with distributors and sales representatives, Defendants did not issue any communications to surgeons who had implanted Device with a recalled polyethylene component or to patients who had received an Device with a recalled polyethylene component until months later in February 2022.

83. On February 7, 2022, Defendants issued an "Urgent Medical Device Correction" in which it informed health care professionals that:

After extensive testing, we have confirmed that most of our inserts manufactured

> since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

See Letter from Darin Johnson, President & CEO, Exactech and Sharat Kusuma, Senior Vice President & Chief Medical Officer, Exactech, to Exactech Surgeons, Urgent Medical Device Correction (Feb. 7, 2022) [hereinafter Exactech Recall Letter], attached hereto as Exhibit A.

84. The "Urgent Medical Device Correction" went on to further state that Defendants were expanding the recall to include all knee arthroplasty polyethylene inserts packed in non-conforming bags regardless of label or shelf life. The components subject to the recall now included: OPTETRAK®: All-polyethylene CR Tibial Components, All-polyethylene PS Tibial Components, CR Tibial Inserts, CR Slope Tibial Inserts, PS Tibial Inserts, HI-FLEX® PS Tibial Inserts; OPTETRACK Logic®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, CC Tibial Inserts; and TRULIANT®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts. *Id.*

85. It is estimated that a total of 147,732 inserts implanted in the United States since 2004 were produced with non-conforming packaging. *Id.*

86. Defendants further acknowledged the original Optetrak knee system has shown statistically significant higher overall revision rates compared to other total knee arthroplasties in the Australian, United Kingdom, and New Zealand joint registries. *Id.*

87. Specifically, reasons for revision associated with polyethylene wear, including loosening, lysis, and pain, were increased three- to seven-fold with the Optetrak total knee

replacement combination of the Optetrak-PS/Optetrak, according to the 2021 Australian National Joint Replacement Registry with revision diagnoses related to accelerated polyethylene wear possibly related to the non-conforming packaging. *Id.*

88. Implanting surgeons were advised in the February 2022 notice to contact patients previously implanted with recalled components and to schedule an evaluation if the patient is experiencing any new or worsening knee swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in the knee. *Id.*

89. Furthermore, Defendants advised surgeons that revision surgery should be considered for patients who exhibit premature polyethylene wear. *Id.*

90. Based on Defendants' own representations, since 2004, Defendants manufactured, promoted, and distributed the Device without ensuring the polyethylene components were properly packaged to prevent or minimize oxidation. At no point until August 2021 did Defendants first modify the packaging in an effort to address this defect.

91. In approximately 2017–2018, Exactech, Inc. was in the process of being acquired by the Private Equity Group TPG Capital, which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all of the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO, and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing ownership of the Company. *See Exactech Announces Completion of Merger with TPG Capital*, EXACTECH (Feb. 14, 2018), https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital (last visited Jan. 21, 2023).

92. Disclosure of knowledge of the improper packaging and excessive premature failure rates could have harmed this transaction.

93. At all times relevant to this action, Defendants were aware of the Devices' propensity to undergo substantial early polyethylene wear consisting of the degradation and breakdown of the plastic chemicals causing toxicity to the tissue and bone and component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery and its attendant complications in patients.

94. At all times relevant to this action, Defendants failed to acknowledge the manufacturing defects in the Device due to poor and inadequate quality assurance procedures and due to a wanton and reckless disregard for public safety. Defendants also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring and quality assessments to ensure the safety of the Device.

95. At the time the Device was manufactured and sold to patients, including Plaintiff, the device was defectively manufactured, packaged and unreasonably dangerous, and did not conform to the federal regulations subjecting patients to unreasonable risks of injury.

96. At all times relevant to this action, Defendants' inadequate manufacturing processes also led to material flaws in the quality systems at its manufacturing, packaging, storage and distribution facilities.

97. During manufacture and distribution of the Device, Defendants failed in several ways, including, without limitation, by:

a. failing to conduct adequate mechanical testing, including oxygen-resistance or other wear testing for the components, subassemblies, and/or finished Device;

b. failing to test an adequate number of sample devices on an ongoing basis;

c. failing to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

d. failing to identify and/or note the significance of any testing that resulted in failure of the Device;

e. failing to take corrective actions to eliminate or minimize further failures of the Device;

f. failing to adequately explain packaging specifications for the components, subassemblies, and/or finished Device;

g. failing to perform adequate quality control before the components, subassemblies, and/or finished Device were distributed;

h. failing to properly address reports from their sales representatives who reported their observations while attending revision surgeries where evidence of polyethylene debris and osteolysis was apparent and noted by the surgeons and the sales representatives themselves;

i. failing to timely implement corrective action and investigations to understand the root cause of these failures while continuing to sell the components knowing they would be implanted into the bodies of thousands of people; and

j. Becoming aware of the potential cause or causes but unreasonably avoiding informing patients and surgeons and delaying the ability to minimize damages as the devices continued to degrade and do damage in the patients' bodies.

98. On or before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known the Device was failing and causing serious complications after implantation in patients. Such complications included, but were not limited to, catastrophic polyethylene wear including the deposition of plastic particulate wear debris throughout the knee, a high rate of component loosening, and overall early system failure resulting in tissue destruction, osteolysis, and other injuries causing severe pain, swelling, instability and dysfunction in the knee and leg necessitating revision surgery.

99. Defendants as manufacturers of orthopedic devices know that each surgery, especially a revision surgery, is always more complicated than an initial knee replacement surgery and is fraught with serious risks of infection, anesthesia errors, dislocations and other serious

complications that should be avoided.

100. Defendants, however, ignored reports of early failures of their Device and failed to promptly investigate the cause of such failures or issue any communications or warnings to orthopedic surgeons and other healthcare providers.

101. Before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known that the Device was defective and unreasonably dangerous to patients, that the product had an unacceptable failure and complication rate, and that the product had a greater propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

TPG DEFENDANTS' ACQUISITION AND CONTROL OF EXACTECH

TPG's Control over the Acquisition of Exactech

102. On October 22, 2017, Exactech Inc. submitted a Form 8-K Report to the SEC, reporting that it had entered into an Agreement and Plan for Merger ("Merger Agreement") with Osteon Holdings, L.P. ("Parent" and same as Defendant Osteon Holdings, Inc.) and Defendant Osteon Merger Sub, Inc., a corporation and wholly owned subsidiary of Parent.

103. The October 22, 2017 Report describes the parties to the merger acquisition and financing of Defendant Exactech Inc.

104. The Merger Agreement stated that Defendants Exactech Inc. and Osteon Merger Sub, Inc. will be merged, and Exactech Inc. will be the surviving entity and a wholly-owned subsidiary of Defendant Osteon Holdings, Inc.

105. Exhibit 10.1 to the October 22, 2017 8-K Report is a letter from Michael LaGatta, setting forth the commitments of TPG Partners VII, L.P., to purchase certain equity interests of Parent ("Letter Agreement").

106. The Letter Agreement was signed by Michael LaGatta on behalf of TPG Partners VII, L.P. and also "Agreed to and Accepted" on behalf of Parent by Michael LaGatta.

107. As noted above, Mr. LaGatta is a full-time employee of TPG who is an active member of numerous TPG entities, having, for example, signed documents in his capacity as Vice President for TPG Global, LLC, TPG Holdings, L.P., TPG Partner Holdings, L.P., TPG Group Advisors (Cayman), Inc., Osteon Holdings, L.P. ("Parent"), and Osteon Merger Sub, Inc.

108. TPG Capital negotiated the terms of the acquisition of Exactech, as it controls Osteon Holdings, L.P. and Osteon Merger Sub, Inc.

109. TPG Capital also organized and directed the financing of the merger acquisition of Exactech through TPG Partners VII, L.P., which served as the financing entity for the merger acquisition and is controlled by TPG Capital.

TPG'S Control over Its Affiliates

110. Osteon Holdings, L.P. and Osteon Merger Sub, Inc. are referred to as "Affiliates" of TPG Capital in SEC filings related to the Merger Acquisition.

111. Specifically, Exactech, Inc. reported to the SEC that "Parent and Merger Sub are affiliates of global private equity firm TPG Capital." Exactech, Inc., Current Report (Form 8-K) (Oct. 22, 2017).

112. Similarly, on December 4, 2017, Exactech reported to the SEC that:

> Exactech, Inc., . . . announced today that it has entered into an amendment to its merger agreement with TPG Capital and certain of its affiliates which was previously announced on October 23, 2017. Pursuant to the amended merger agreement, the Company's common stock outstanding immediately prior to the effective time of the merger . . . will be converted into the right to receive $49.25 per share in cash. This represents an increase of approximately 17.3% over the $42.00 per share merger consideration previously agreed to by Exactech and TPG Capital. TPG Capital has also increased its equity financing commitment to $737 million for purposes of consummating the merger.
>
> Exactech's Board has approved the amended merger agreement with TPG and has determined that it is advisable, fair to and in the best interest of Exactech and its

> shareholders. Exactech's Board hereby recommends to Exactech's shareholders that they vote to approve the merger agreement and the merger with TPG.
>
> TPG has arranged fully committed equity financing for the transaction and there is no financing condition to consummation of the merger with the Company. Early termination of the statutory waiting period under the Hart-Scott-Rodino Act was obtained on November 17, 2017 and, accordingly, there are no anti-competitive or other regulatory approvals needed to consummate the merger with TPG Capital's affiliate.

113. In a Form 8-K, dated February 13, 2018, filed with the SEC, Exactech, Inc. reported:

> On February 14, 2018 (the "Closing Date"), pursuant to the terms of that certain Agreement and Plan of merger, dated as of October 22, 2107 (the "Original Merger Agreement"), as amended by Amendment No. 1 thereto ("Amendment No. 1 to Merger Agreement"), dated as of December 3, 2017 (as to amended, the "Merger Agreement") . . . the Company [Exactech, Inc.] became indirectly beneficially wholly owned by affiliates of TPG Capital (the "TPG Investors") and certain management shareholders of the Company.

114. The Securities Act of 1933 defines an Affiliate as an entity that "directly, or indirectly through one or more intermediaries, **controls or is controlled by**, or is under common control with, the person [entity] specified." 17 C.F.R. § 230.405 Definitions of terms (emphasis added).

115. Osteon Holdings, L.P. ("Parent") and Osteon Merger Sub, Inc. were the corporate vehicles used by TPG Capital to consummate the merger with Exactech, Inc.

116. Both of these entities were affiliates of TPG Capital and, therefore, controlled by TPG Capital under the definition of "Affiliate" as set forth in the Securities Act of 1933.

117. Since Osteon Merger Sub, Inc. was "merged with and into Exactech, Inc.," Exactech, Inc. is considered an affiliate controlled by TPG Capital, pursuant to the merger transaction. TPG Capital accordingly is liable for the improper actions of Exactech that occurred prior to the Merger and also actions that Osteon was aware of and directed subsequent to the Merger.

Osteon Holdings' Conversion: Osteon Holdings, L.P. to Osteon Holdings, Inc.

118. In connection with the Exactech Merger, on or about October 22, 2017, a Rollover and Voting Agreement was executed, naming William Petty, Betty Petty, David W. Petty, and Prima Investments Limited Partnership (f/k/a Petty Family Investments, LP) as Shareholders in Osteon Holdings, L.P. Osteon Holdings L.P. was the "Parent" to the Merger.

119. On or about December 3, 2017, an amendment to this Rollover and Voting Agreement, was executed.

120. As part of the December 3, 2017 amendment ("Amendment 1"), Miller Family Holdings, LLC[2], Bruce Thompson, Joel Phillips, Donna Edwards, Chris Roche, and Steve Szabo became shareholders in Osteon Holdings, L.P.

121. According to Schedule A-1 of Exhibit A of the Rollover and Voting Agreement, only those listed on the Agreement, i.e., Exactech pre-merger executives and officers, received subject shares in Osteon Holdings, L.P., in exchange for some of their Exactech shares in the Exactech Merger. For example, Dr. William Petty held 102,400 rollover shares in the Exactech Merger, which were exchanged for 5,821,546 shares of Class B common stock of Osteon Holdings L.P.

122. Osteon Holdings, L.P. was a limited partnership. Under basic tenets of corporate law, Limited Partnerships do not have stock or stockholders. A Limited Partnership has a general partner, who takes unlimited liability for a company's obligations, and one or more limited partners – whose liabilities are limited to the size of their investments.

123. On or about February 14, 2018, an amendment to the closing Transaction Statement (the "Final Amendment") was executed in connection with the Exactech Merger.

124. Prior to the execution of the Final Amendment, all original merger agreements and amendments referred to the Parent as Osteon Holdings, L.P.

[2] Miller Family Holdings, LLC is a Florida limited liability company wholly owned by Dr. Gary Miller, his wife, and his children).

125. In the Final Amendment, the Parent is no longer referred to as Osteon Holdings L.P. Instead, the Final Amendment refers to the Parent as Osteon Holdings Inc.

126. There is no disclosure explaining why the original Parent company, Osteon Holdings L.P. was converted to Osteon Holdings Inc.

TPG's Complete Control over Rollover & Voting Agreement Negotiations with Exactech

127. During the merger negotiations between April 2017 and December 2017, including various amendments to original agreements, Exactech's Executive Chairman Dr. William Petty and founding shareholders ("the Rollover Investors") "had been approached by and had held discussions with TPG . . . to inquire whether such shareholders would be willing to exchange, in connection with the merger, a portion of their shares of Common Stock for a new class of equity securities in [Osteon Holdings]," an affiliate of TPG. *See* Exactech, Inc., Proxy Statement (Form DEF 14A), at 34 (Jan. 16, 2018).

128. "As a condition to receiving new equity securities in [Osteon Holdings], the Rollover Investors have agreed to vote all of their shares of Common Stock [in Exactech] "FOR" the proposal to approve the Merger Agreement and the merger [with TPG]." *Id.* at 96.

129. "TPG and [its outside Counsel] Ropes & Gray, exchanged seven drafts of the Original Merger Agreement, as well as multiple issues lists, and held multiple telephonic conferences to discuss and negotiate the terms and conditions of the Original Merger Agreement. . ." and reviewed several drafts of the Original Rollover & Voting Agreement ("Rollover Agreement"). *Id.* at 29-30.

130. As a result of these discussions, Osteon Holdings and the pre-merger Exactech Chairman, founding shareholders and other officers, executed the Rollover Agreement on October 22, 2017, as amended on December 3, 2017.

131. The Amended Rollover Agreement added an "automatic conversion" paragraph that allowed Exactech's Chairman, founding shareholders, and other officers to automatically

convert their individually owned shares in Osteon Holdings "immediately prior to an initial public offering" to shares in an anticipated Initial Public Offering ("IPO") involving TPG, its partners, and affiliates.

132. TPG, Inc. completed its IPO on January 13, 2022.

133. Osteon Holdings, a TPG controlled affiliate and party to the Rollover Agreement, had no authority to commit future TPG IPO shares through an automatic conversion to Osteon Holdings shareholders.

134. TPG Capital, LP, through its common officers with its affiliates, had the authority to implement the automatic conversion of future shares under the anticipated IPO plan, since TPG, Inc. did not exist at the time the Rollover Agreement was executed.

135. TPG Capital, LP officers are also officers of Osteon Holdings. In effect, TPG and its affiliates operate as a single enterprise under the global brand name, "TPG." Furthermore, as demonstrated by the Rollover Agreement and the Exactech January 16, 2018 Proxy Statement, TPG Capital, LP controlled Osteon Holdings and the negotiations related to the Exactech merger through its common officers, general counsel, and outside counsel.

TPG's Control over the Management Agreement

136. Per the 2017 Amendment to the Rollover and Voting Agreement, Exactech would operate using TPG's "customary management agreement." This management agreement did not require unanimous consent from the Exactech board. This is notable, because as set forth below, TPG placed many of its own employees on Exactech's Board and in key positions throughout the company.

137. TPG requiring Exactech to use of its own management agreement demonstrates that TPG has control over the management of Exactech.

138. The 2017 Amendment to the Rollover and Voting Agreement also said that employment agreements with TPG or its affiliates did not require unanimous consent from the Exactech board.

139. TPG requiring control of employment agreements that involve any affiliates demonstrates that it has direct control over employees at Exactech.

Co-Mingling Liability

140. The Merger Agreement demonstrates that the parent company, Osteon Holdings, Inc., assumed certain liabilities of the acquired company, Exactech.

141. The Merger Agreement provides that Defendants Exactech and Osteon Holdings, Inc. will jointly participate in the defense or settlement of any security holder litigation against Exactech or its directors related to the merger.

142. The Merger Agreement provides that Exactech cannot enter into any settlement agreement regarding any securityholder litigation against it or its directors relating to particular transactions without Osteon Holdings' prior written consent.

143. Osteon Holdings and TPG are named as affiliates and grouped together as "the TPG Parties" in the Final Amendment of the SEC Rule 13E-3 Transaction Statement that they jointly filed with Exactech on February 14, 2018.

144. On the SEC's Notice of Exempt Offering of Securities, six directors and seven officers of TPG are listed as "related persons" in connection with Osteon Holdings.

145. Osteon Holdings and TPG, as "the TPG parties," should be grouped together for purposes of liability under the Merger Agreement.

146. The language of the Merger Agreement and SEC filings demonstrates that the TPG parties and Exactech co-mingle liabilities, share economic resources, and conduct and manage operations through their common officers and directors.

TPG's Post-Acquisition Control of Exactech

147. TPG is not a passive investor in Exactech.

148. TPG has undertaken active management of Exactech as part of its ownership of the company.

149. TPG promotes its "distinctive," "alternative," and "unique" approach to growing the companies that it invests in.

150. Part of TPG's promoted approach is being "involved in building really special companies."

151. "Building really special companies" requires more than providing money.

152. Another part of TPG's promoted "unique approach" is bringing a "family office" and "entrepreneurial" perspective to the companies that it partners with.

153. TPG promotes its ability to "create products and services [that have] delivered breakthrough innovation" in the healthcare industry.

154. In the healthcare industry specifically, TPG emphasizes its "differential insights."

155. TPG played an active role in selecting the people who would run the day-to-day operations of Exactech after the merger.

156. In meetings during June and July of 2017, TPG told Exactech that it was important for Jeffrey R. Binder (a TPG advisor) to have a central role in any potential transaction between Exactech and TPG.

157. Jeffrey R. Binder and Daniel Hann both advised TPG Capital on its acquisition of Exactech.

158. Jeffrey R. Binder became CEO of Exactech in March 2022 after joining Dr. William Petty as co-executive Chairman of Exactech in 2018.

159. Daniel Hann became Senior Vice President of Business Development of Exactech.

160. After an Exactech Board of Directors meeting in September 2017, the company's lead independent director, Mr. James G. Binch, contacted another director, Mr. Todd Sisitsky (TPG President and Co-Managing Partner), to tell him that TPG was now permitted to speak with Exactech's founding shareholders and management team regarding equity participation, employment, and other arrangements for after the merger.

161. Eleven pre-merger officers or directors of TPG became officers or directors of Exactech post-merger.

162. TPG advisors have continued to exert direct control over Exactech since the merger.

163. Defendant Osteon Intermediate Holdings II, Inc. is the certificate holder on a Certificate of Insurance associated with Exactech, Inc. Coverage held by Osteon Intermediate Holdings II, Inc. includes, but is not limited to, products liability.

164. TPG advisors have served in at least six leadership positions for Exactech: three officer positions-filled by Jeffrey R. Binder, Daniel P. Hann, and Kerem Bolukbasi-and three director positions-filled by Kendall Garrison, John Schilling, and Todd Sisitsky.

165. One-third of the nine-member Exactech Board of Directors is composed of TPG employees.

166. As further evidence of TPG's control over Exactech, orthopedic surgeons may be incentivized to utilize Exactech products in exchange for shares of Osteon Holdings. For example, in a 2021 American Association of Hip and Knee Surgeon disclosure report, a Massachusetts-based orthopedic surgeon who is an Exactech "paid consultant" with "IP royalties" disclosed that he has "stock or stock options" in Osteon Holdings.

TPG's Direct Involvement in Decision Making Related to the Recall of Exactech's Hip, Knee, and Ankle Devices

167. Upon information and belief, TPG advisors and Officers directed the Exactech Hip, Knee, and Ankle Device recalls caused by accelerated polyethylene wear.

168. TPG Officers and Directors are also Officers and Directors of Osteon Holdings and Exactech. Therefore, TPG was directly involved in decision making related to the recalls.

169. Upon information and belief, in 2017 or 2018, during due diligence prior to the acquisition of Exactech or shortly after acquiring Exactech, TPG knew or should have known of the clinical evidence of early onset failures of Exactech Devices and Exactech's non-compliance with federal regulations and current good manufacturing practices.

170. Public records reveal that Exactech had a history of device failures that may have required a voluntarily recall before the merger and after the merger.

171. Upon information and belief, in order to increase the value of TPG's ownership of Exactech, TPG chose to continue selling Exactech Hip, Knee, and Ankle Devices despite research and clinical evidence demonstrating significant product defects that were harming patients with those devices implanted in their bodies.

172. TPG's involvement in Exactech presentations after the merger demonstrates that TPG was aware of the clinical evidence of early onset failures of the Exactech Devices and participated in the corrective action plan.

173. The first recall of Optetrak devices was not issued until August 30, 2021, over three years after the 2018 Merger.

174. In November 2021, Exactech CFO and Treasurer Kerem Bolukbasi ("Bolukbasi') gave a "cash flow profile" presentation to the Exactech Board of Directors, including TPG board members and advisors, regarding the August 2021 Exactech recall which "created significant financial difficulty for Exactech . . . reflecting an estimated $60 million cash burn during 2022."[3]

175. Following this presentation and disclosure Bolukbasi was terminated by TPG and Exactech.

176. To effectuate Bolukbasi's termination, Darrin Johnson conferred with TPG employee, and Exactech board member, John Schilling.

177. Also in November 2021, Karen Golz, a member of the Exactech Board of Directors, was appointed to the Board of Directors of another company, iRobot. The iRobot press release announcing Ms. Golz's appointment stated that Ms. Golz also serves on the Board of Directors of "Osteon Holdings/Exactech, a private company controlled by TPG."

178. At all stages, TPG has been directly involved in and controlled the decision making regarding when and how to recall Exactech's defective Hip, Knee, and Ankle Devices and alert

[3] A cash burn means that the company would be forced to spend large sums of money in connection with the August 2021 recall.

the patients and surgeons to Exactech's years' long failure to manufacture safe devices and comply with good manufacturing practices.

JOSEF BEER'S IMPLANTS AND REVISION SURGERIES

179. On May 24, 2010, Plaintiff JOSEF BEER underwent a right total knee replacement surgery at the Hospital for Special Surgery (HSS) in New York, New York where he was implanted with a recalled Optetrak CC Polyethylene Tibial Insert (Serial #: 1003013).

180. On August 2, 2010, Plaintiff JOSEF BEER underwent a left total knee replacement surgery at the Hospital for Special Surgery (HSS) in New York, New York where he was implanted with a recalled Optetrak CC Polyethylene Tibial Insert (Serial #: 1422412).

181. On May 6, 2019, Plaintiff JOSEF BEER underwent bilateral total knee revision surgeries at HSS Stamford in Stamford, Connecticut, due to accelerated and preventable where of the Optetrak CC Polyethylene Tibial Insert components. During Plaintiff's bilateral total knee revision surgery, Plaintiff JOSEF BEER was implanted with recalled Optetrak Logic PSC Polyethylene Tibial Insert components in each knee (Serial # 2916906; 5118362).

182. As a consequence of Plaintiff's May 6, 2019 revision surgery, Plaintiff developed an infection in his left knee and required five additional surgeries on his left knee to treat the infection and additional complications stemming from the failure of the recalled Optetrak component implanted in his left knee.

183. To date, Plaintiff JOSEF BEER continues to have a recalled Optetrak Device implanted in his right knee and he may require a re-revision surgery in the future.

184. Defendants, through their affirmative misrepresentations and omissions, actively and fraudulently concealed from Plaintiff and Plaintiff's health care providers the true and significant risks associated with the Device and the need to vigilantly do diagnostic procedures to

promptly diagnose the insidious process of the toxic polyethylene particles degrading and causing osteolysis.

185. Defendants know that after the one-year checkup following a total knee arthroplasty, typically patients are not expected to return for monitoring absent problems. Thus, Defendants knew that—unless they informed surgeons to call their patients back for periodic radiologic monitoring—polyethylene chemical degradation and attendant osteolysis could be occurring unchecked until it reached the stage of severe bone loss.

186. As a direct, proximate, and legal consequence of the defective nature of the Device as described herein, Plaintiff JOSEF BEER has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

187. As a further direct, proximate, and legal consequence of the defective nature of the Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

TOLLING OF STATUTE OF LIMITATIONS

A. Latent Injury

188. To the extent it is claimed that Plaintiff suffered symptoms prior to undergoing revision surgery, the statute of limitations is tolled because development of osteolysis, bone loss, and device loosening are latent conditions caused by years of exposure to toxic polyethylene wear debris that could not be appreciated until the date Exactech disseminated the information justifying its recall of the Exactech Knee Devices.

189. As a plastic, polyethylene wear debris contains chemicals or additives and may contain impurities such as catalyst residues, unreacted monomers, or breakdown products which possess toxic properties that can adversely affect human health. *See* Matthias C. Rillig et al., *The Global Plastic Toxicity Debt*, 55 ENV'T. SCI. & TECH. 2717, 2717–19 (2021).

190. As described above, such toxic effects on the human body include, but are not limited to, osteolysis, tissue necrosis, and destruction of the bony integration between the component parts of the prosthetic and the patient's anatomy.

191. Prior to Exactech initiating its recall and disseminating information about the recalls to Plaintiff, technical, scientific, or medical knowledge and information sufficient to ascertain the cause of the failure of the Exactech Knee Devices had not been known.

192. Thus, Plaintiff exhibited due diligence and did not possess "technical, scientific, or medical knowledge" and information sufficient to ascertain the cause of the injuries until after Exactech recalled their Knee Devices.

B. Fraudulent Concealment

193. Exactech, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the defects in and true and significant risks associated with Exactech's Knee Devices, claiming any failures were due to surgical technique, positioning, or patient characteristics.

194. Following implantation of the Device, Plaintiff and Plaintiff's healthcare providers relied on Exactech's continued representations that the Devices, including their polyethylene components, had excellent long-term clinical outcomes.

195. Exactech made these representations with knowledge of their falsity, an intent to defraud, and/or disregard for the truth given its knowledge of reports of high failure rates.

196. Furthermore, following implantation of the Device, Plaintiff and Plaintiff's healthcare providers relied on Exactech to provide them with urgent safety information regarding Exactech's Hip, Knee, and Ankle Devices, including recalls, communications regarding defects and increased rates of failure, and warnings and instructions on how to assess, diagnose, and mitigate risks associated with the defects in these Devices.

197. Although clinical evidence demonstrated that the polyethylene used in Exactech Knee Devices was failing at a rate higher than promoted, with instances of excessive revision rates due to device loosening and polyethylene wear, Exactech failed to initiate recalls earlier or issue any communications to healthcare providers that the Devices were defective and patients should be monitored.

198. Until recently, Exactech lacked highly-crosslinked polyethylene for its Hip, Knee, or Ankle Devices. Accordingly, without a viable substitute, earlier disclosure of these failure rates could have negatively impacted Exactech's ongoing business and sale to TPG in 2017/2018.

199. As a result of Exactech's actions, omissions, and misrepresentations, Plaintiff and Plaintiff's healthcare providers were unaware, and could not have reasonably known, learned, or discovered that any Plaintiff's symptoms or radiological findings indicative of a potential problem with Plaintiff's joints were the result of defects in Exactech's Knee Devices.

200. Furthermore, had Exactech not actively concealed evidence of growing reports of accelerated polyethylene wear and Device failures, Plaintiff's surgeon would have not implanted Exactech device, and for those patients already implanted with Exactech devices, their surgeons would have initiated monitoring for device failures at an earlier time.

201. Such intervention would have led to an earlier diagnosis of loosening and bone loss, and earlier removal of the Devices, thereby reducing damage to bone and tissue.

202. As a result of Exactech's actions, omissions, and misrepresentations, many individuals underwent revision surgeries during which they received new Exactech polyethylene components, subjecting them to a new exposure to the defective polyethylene and the need for yet another revision in the following years, while Exactech profited from selling more of its products.

203. As a result of Exactech's actions, omissions, and misrepresentations, Plaintiff and Plaintiff's healthcare providers were unaware, and could not have reasonably known, learned, or discovered through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the result of defects in Exactech's Hip, Knee, and Ankle Devices.

204. Accordingly, no limitations period should accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with Exactech's Knee Device, and the resulting harm later suffered by Plaintiff as a result and by reason of Exactech's fraudulent concealment.

205. Additionally, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described herein.

206. Further, the limitations period should be tolled under principles of equitable tolling.

CAUSES OF ACTION PURSUANT TO
THE NEW JERSEY PRODUCT LIABILITY ACT
N.J. Stat. § 2A:58C-2 *et seq.*

FIRST CAUSE OF ACTION
STRICT LIABILITY—MANUFACTURING DEFECT

(Against Exactech Defendants and TPG Defendants[4])

207. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

208. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

209. The Defendants had a duty to manufacture the Device in a manner that prevents unreasonable risk of harm or injury to users and patients, including Plaintiff.

210. The Defendants had a duty to distribute, market, and/or sell the Device without manufacturing and related packaging defects to prevent an unreasonable risk of harm or injury to users and patients, including Plaintiff.

211. The Devices manufactured by the Defendants were not reasonably safe for their expected, intended, and/or foreseeable uses, functions, and purposes.

212. The Devices were not reasonably safe as manufactured, packaged, distributed, marketed and/or sold by the Defendants.

213. The defects in manufacture of the Device were a substantial factor in causing Plaintiff's injuries.

[4] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

214. At all times herein mentioned, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in manufacture. The defects in manufacture include but are not limited to:

a. failure to package the polyethylene components of the Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery;

b. the materials used to package the Device were of an inferior grade or quality;

c. that the Device as manufactured differed from Defendants' intended specifications;

d. that Defendants failed to measure and/or test an adequate number of samples of Devices on an ongoing basis;

e. that Defendants failed to take corrective actions to eliminate or minimize further failures of the Device;

f. that Defendants failed to perform adequate quality control or other such testing on the polyethylene inserts used in the Device to ensure they complied with required specifications and were not prematurely degrading while stored;

g. failure to select appropriate third parties to package the polyethylene inserts used in the Device;

h. failure to properly supervise and monitor the packaging of the polyethylene inserts used in the Device;

i. failure to exercise sufficient quality control to ensure the polyethylene inserts in the Devices were safe for implantation in users and patients and would not degrade abnormally under average and regular use; and

j. that Defendants violated applicable state and federal laws and regulations; and in all other ways.

215. Defendants knew or reasonably should have known and been aware that the

Devices were defectively manufactured.

216. The manufacturing defects in the Device existed when the device left the Defendants' control.

217. Plaintiff's physicians implanted the Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

218. The Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

219. As alleged herein, Defendants knew or had reason to know that the Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

220. The manufacturing defects of the Device presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

221. The manufacturing defects of the Device presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

222. Plaintiff could not, by the exercise of reasonable care, have discovered the manufacturing defect and perceived its dangers or avoided injury.

223. The Defendants are strictly liable for the defective manufacture of the Device; the distribution, marketing, and/or sale of the defectively manufactured Device; and the injuries

sustained by Plaintiff.

224. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

225. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

226. As a direct, proximate, and legal consequence of the defective nature of the Device as described herein Plaintiff JOSEF BEER has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

227. As a further direct, proximate, and legal consequence of the defective nature of the Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

228. Defendants acted intentionally, recklessly, and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT LIABILITY—DESIGN DEFECT

(Against Exactech Defendants and TPG Defendants[5])

229. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

230. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

231. Defendants had a duty to design and package the Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

232. Defendants had a duty to distribute, market, and/or sell the Device with a design that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

233. The design of the Device and corresponding packaging is defective and not reasonably safe for its expected, intended, and/or foreseeable uses, functions, and purposes.

234. The Device and corresponding packaging are not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendants.

235. The defective design of the Device and packaging received by Plaintiff's implanting surgeon was a substantial factor in causing Plaintiff's injuries.

[5] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

236. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in design. The defects in the design include but are not limited to:

a. that the Device has propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients;

b. failure to design the packaging for the polyethylene components of the Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery;

c. that the materials used within the Device and packaging were of an inferior grade or quality than advertised and promoted by Defendants;

d. Defendants failed to conduct adequate testing, including wear or other testing, on components, subassemblies and/or the finished Device as packaged and distributed;

e. Defendants failed to test an adequate number of samples of Devices on an ongoing basis;

f. Defendants failed to take adequate steps to specifically identify failure modes with the Device with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

g. Defendants failed to identify and/or note the significance of any testing that resulted in failure of the Device;

h. Defendants failed to take corrective actions to eliminate or minimize further failures of the Device;

i. Defendants failed to adequately design packaging specifications for the components, subassemblies, and/or the finished Device;

j. The polyethylene material used in the Device in conjunction with the

inferior vacuum bags caused and/or contributed to the devices having a higher failure rate than other similar devices available at the time the Devices were put on the market;

k. The polyethylene material used in the Device in conjunction with the inferior vacuum bags caused and/or contributed to the devices having a shorter effective lifetime than other similar devices available at the time the Devices were put on the market;

l. The Defendants' method of designing the polyethylene insert and packaging increased the risk of users and patients suffering from pain, discomfort, injury, and the need for revision surgery; and

m. that Defendants violated applicable state and federal laws and regulations; and in all other ways.

237. Defendants knew or reasonably should have known and been aware that the Devices and packaging were defectively designed.

238. The design defects in the Device and packaging existed when the device left the Defendants' control.

239. Plaintiff's physicians implanted the Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

240. The Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

241. As alleged herein, Defendants knew or had reason to know that the Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

242. The Device and packaging as designed carried risks that were outweighed by any utility of the design of the device and packaging because when paired together, the Device and packaging

were dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Device and the packaging in which it was received were in a condition not suitable for proper and intended use.

243. The Device and packaging were defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

244. Feasible safer alternative designs providing the same functional purpose were available to the Defendants at the time the Device was designed and packaged and offered for sale in the market.

245. For example, Defendants could have utilized vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the polyethylene components from undergoing increased oxidation according to their own admissions.

246. The design defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

247. The design defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

248. Plaintiff could not, by the exercise of reasonable care, have discovered these design defects and perceived their dangers or avoided injury.

249. The Defendants are strictly liable for the defective design of the Device; defective design of the packaging of the Device; the distribution, marketing, and/or sale of the Optetrak Device; and the injuries sustained by Plaintiff.

250. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

251. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

252. As a direct, proximate, and legal consequence of the defective nature of the Device as described herein, Plaintiff JOSEF BEER has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

253. As a further direct, proximate, and legal consequence of the defective nature of the Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

254. Defendants acted intentionally, recklessly, and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiffs to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
STRICT LIABILITY—FAILURE TO WARN

(Against Exactech Defendants and TPG Defendants[6])

255. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

256. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

257. Defendants had a duty to provide adequate warnings regarding the Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

258. Defendants had a duty to distribute, market, and/or sell the Device with adequate warnings that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

259. The warnings that accompanied the Device and corresponding packaging were defective, thereby making the product not reasonably safe for its expected, intended, and/or foreseeable uses, functions and purposes.

260. The Device and corresponding packaging are not reasonably safe as labeled, distributed, marketed, delivered and/or sold by Defendants.

261. Inadequate labeling accompanying the Device and packaging received by Plaintiff's implanting surgeon was a substantial factor in causing Plaintiff's injuries.

[6] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

262. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective.

263. The Device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendants or its sales force to physicians and patients with or about the Device failed to adequately convey the potential risks and side effects of the Device and the dangerous propensities of the device, which risks were known or were reasonably scientifically knowable to Defendants.

264. In particular, Defendants failed to adequately disclose the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, bone loss, osteolysis, and other injuries as well as the need for revision surgery in patients.

265. Defendants consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Device; and continuing to market, promote, sell, and defend the Device until the very recent recall.

266. Defendants knew or reasonably should have known and been aware that the Devices and packaging contained inadequate warnings.

267. The inadequate warnings for the Device existed when the device left the Defendants' control.

268. Plaintiff's physician implanted the Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

269. The Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

270. As alleged herein, Defendants knew or had reason to know that the Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

271. The Device that was labeled, manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably dangerous to any user or ordinary consumer of the device, including Plaintiff.

272. The labeling defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

273. The labeling defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

274. Plaintiff could not, by the exercise of reasonable care, have discovered these defects and perceived their dangers or avoided injury.

275. Defendants failed to issue new warnings or initiate a recall in a timely manner as to help minimize the damage and bone loss occurring in patients, including Plaintiff.

276. The Defendants are strictly liable for providing inadequate warnings accompanying the Device and packaging of the Device; the distribution, marketing, and/or sale of the Device; and the injuries sustained by Plaintiff.

277. By reason of the foregoing acts, omissions, and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

278. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

279. As a direct, proximate, and legal consequence of the defective nature of the Device as described herein, Plaintiff JOSEF BEER has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

280. As a further direct, proximate, and legal consequence of the defective nature of the Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

281. Defendants acted intentionally, recklessly, and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiffs to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as

the Court deems proper.

FOURTH CAUSE OF ACTION
NEGLIGENCE

(Against Exactech Defendants and TPG Defendants[7])

282. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

283. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

284. Prior to, on, and after the dates of Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution, and sale of the Device for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

285. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution, and sale of the Device.

286. Following Plaintiff's initial knee surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in failing to recall the Device.

287. At all times material hereto, the Defendants had actual knowledge, or in the

[7] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with the Device.

288. Defendants had access to registry data and were aware of complaints that the Device caused serious complications including but not limited to polyethylene wear and/or other failure causing serious complications including component loosening, tissue damage, osteolysis, bone loss and the need for revision surgery in patients.

289. Despite the fact that Defendants knew or should have known the Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Device for implantation into consumers.

290. Despite the fact that Defendants knew or should have known the Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Device for implantation into consumers without revising any warning language or issuing an earlier recall.

291. Defendants failed to advise surgeons and patients of the need for regular follow-up—beyond the ordinary practices after a total knee implant—to promptly detect polyethylene degradation and osteolytic failure and timely revise the device to prevent or at least minimize bone loss, osteolysis and related injuries.

292. Defendants failed to exercise due care under the circumstances, and their gross negligence and recklessness includes the following acts and omissions:

a. Negligently failing to properly package the polyethylene components of the Device;

b. Negligently failing to select appropriate third parties to package the polyethylene inserts used in the Device;

c. Negligently failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Device;

d. Negligently failing to properly and thoroughly select the material that would be used in the packaging of the Device;

e. Negligently failing to properly and thoroughly select the materials that would be used in the Device;

f. Negligently failing to properly and adequately test the Device and their attendant parts before releasing the devices to market;

g. Negligently failing to conduct sufficient post-market testing and surveillance of the Device;

h. Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Device in accordance with good practices;

i. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Device;

j. Continuing to negligently manufacture, and distribute the Device after the Defendants knew or should have known of their adverse effects and/or the increased early onset failure rates;

k. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Device to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Device;

l. Negligently failing to notify and warn the public, including Plaintiff, and physicians of reported incidents involving injury and the negative health effects attendant to the use of the Device;

m. Negligently misrepresenting the safety of the Device;

n. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Device;

o. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early degradation of the polyethylene substance in the Device;

p. Negligently failing to exercise due care in the advertisement and promotion of the Device;

q. Negligently disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Device;

r. Aggressively promoting the Device without proper warnings of the risk of early failure or material degradation in the average user;

s. Aggressively promoting the Device even after Defendants knew or should have known of the unreasonable risks from implantation;

t. Negligently failing to warn consumers, doctors, users and patients that the Device would contain polyethylene materials not properly packaged and/or in accordance with Defendants' specifications;

u. Negligently diminishing or hiding the risks associated with the implantation of the Device;

v. Negligently failing to recall the Device at an earlier date and institute a process to have patients notified; and

w. Negligently violating applicable state and federal laws and regulations; and in all other ways.

293. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Implants, and otherwise distributing the Device.

294. By reason of the foregoing acts, omissions, and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

295. By reason of the foregoing acts, omissions, and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

296. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale,

and distribution of the Device, Plaintiff JOSEF BEER was implanted with the Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

297. As a further direct, proximate, and legal consequence of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution of the Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

298. Defendants acted intentionally, recklessly, and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiffs to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

(Against Exactech Defendants and TPG Defendants[8])

299. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

300. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

[8] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

301. Defendants owed a duty to orthopedic surgeons, other healthcare providers and to consumers of the Device, including Plaintiff, to accurately and truthfully represent the risks of the Device. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's orthopedic surgeon, the medical community, Plaintiff, and the public about the risks of the Device, including the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, which Defendants knew or in the exercise of diligence should have known.

302. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Device knew, or reasonably should have known, that health care professionals and consumers of the Device would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting the Device.

303. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Device knew, or reasonably should have known, that the patients implanted with Device would suffer early failure and require revision surgery because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

304. The Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the quality and longevity of the Device was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

305. Among Defendants' numerous misrepresentations and misleading omissions are Defendants' assurances that the Device was safe, had an excellent performance record, and did not have a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

306. Despite their knowledge of serious problems with the Device, Defendants urged their sales representatives to continue marketing the Device, and distributed medical literature, white papers, non-peer-reviewed studies, and other communications to surgeons in an effort to mislead them and the general public about the risks associated with the Device and instead create the image and impression that the Device was safe.

307. Defendants made such statements even after they became aware of numerous and serious complications with the Device. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data.

308. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Device.

309. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made.

310. Misrepresentations spanned a number of years, but also include the critical time period of 2017–2018 when the company was in the process of being acquired by the Private Equity Group TPG Capital, which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all of the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing

ownership of the Company. *See Exactech Announces Completion of Merger with TPG Capital*, EXACTECH (Feb. 14, 2018), https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital (last visited Jan. 21, 2023).

311. After the merger in 2018, it still took four years for Defendants to reveal the product defects and their health consequences to the medical community and to the patients, including Plaintiff, even though the key officers of Exactech generally continued with their roles in the newly merged company.

312. Defendants failed to exercise ordinary care in making their representations concerning the Device and, in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Device.

313. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

314. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

315. As a direct and proximate result of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Device, Plaintiff JOSEF BEER was implanted with the Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

316. As a further direct, proximate, and legal consequence of Defendants' acts and

omissions, including Defendants' negligent misrepresentations regarding the Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

317. Defendants acted intentionally, recklessly, and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiffs to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against Exactech Defendants and TPG Defendants[9])

318. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

319. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

320. Defendants expressly warranted that the Devices, including the Optetrak Comprehensive Total Knee System, were safe and effective orthopedic devices.

321. Defendants promised that the Device had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the

[9] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

Optetrak knee system."

322. At the time Defendants manufactured, marketed, sold and/or distributed the Devices, they knew that the devices were intended for human use, and that Plaintiff was a foreseeable user of the Device.

323. The express warranties represented by Defendants were a part of the basis for Plaintiff's use of the Devices, and he and his surgeon relied on these warranties in deciding to use the Device.

324. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Device was to be used and warrantied the same to be in all respects safe, effective and proper for such purpose.

325. The Device did not conform to these express representations, as demonstrated by the fact that Plaintiff's implant failed prematurely due to polyethylene wear of the tibial insert which necessitated him to undergo revision surgery.

326. At the time Defendants marketed, sold and/or distributed the Devices, Defendants expressly warranted that the total knee replacement systems, including all of their component parts, were safe and merchantable for their intended use.

327. Plaintiff JOSEF BEER and his implanting physician reasonably relied upon Defendants' express warranties.

328. Plaintiff JOSEF BEER used the Device for its intended purpose, and in a reasonable, foreseeable manner.

329. The Device manufactured and sold by Defendants, did not conform to Defendants' express representations because the Device caused serious injury to Plaintiff when used as recommended and directed.

330. As a direct and proximate result of Defendants' acts and omissions, including breach of express warranty, Plaintiff JOSEF BEER was implanted with the Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

331. As a further direct, proximate, and legal consequence of Defendants' acts and omissions, including breach of express warranty, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

332. Defendants acted intentionally, recklessly, and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiffs to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

(Against Exactech Defendants and TPG Defendants[10])

333. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

334. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation

[10] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

335. Defendants impliedly warranted, through its marketing, advertising, distributors and sales representatives, that the Device was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

336. In fact, the Device was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

337. The Device manufactured and supplied by Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the components to be properly packaged and stored as to avoid premature degradation of component materials.

338. Plaintiff JOSEF BEER and/or his physician reasonably relied upon the skill and judgment of Defendants as to whether the Device was of merchantable quality and safe for its intended and particular use and purpose.

339. Contrary to such implied warranties, the Device was not of merchantable quality or safe for its intended and particular use and purpose, because Defendants failed to package the polyethylene components of the Device in vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

340. As a direct and proximate result of Defendants' acts and omissions, including breach of implied warranties, Plaintiff JOSEF BEER was implanted with the Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental

anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

341. As a further direct, proximate, and legal consequence of Defendants' acts and omissions, including breach of implied warranties, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

342. Defendants acted intentionally, recklessly, and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiffs to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
LOSS OF CONSORTIUM AND SERVICES
(Against Exactech Defendants and TPG Defendants[11])

343. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

344. At all relevant times, Plaintiff SHEILA BEER was and is the lawfully wedded wife of Plaintiff JOSEF BEER, and as such, was and is entitled to the services, consortium, and society of Plaintiff JOSEF BEER.

345. As a result of the foregoing strict products liability, negligence, and breach of warranties by the defendants, SHEILA BEER, was deprived of the services, consortium, and society of Plaintiff JOSEF BEER.

346. As a direct, proximate, and legal consequence of Defendants' wrongful conduct as

[11] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

described herein, whether through strict liability or negligence, Plaintiff SHEILA BEER has suffered and will continue to suffer the loss of support, companionship, service, love, affection, society, intimate relations, and other elements of consortium all to the detriment of their marital relationship for which Plaintiff SHEILA BEER is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION
PUNITIVE DAMAGES

347. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

348. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

349. At all times material hereto, Defendants knew or should have known the Optetrak Device was inherently more dangerous with respect to the risk of premature polyethylene wear and a shorter life span and need for additional surgeries compared to other knee replacement systems.

350. At all times material hereto, Defendants attempted to misrepresent, and did misrepresent, facts concerning the safety of the Optetrak Device.

351. Defendants' misrepresentations included knowingly withholding material

information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the Optetrak Device.

352. At all times material hereto, Defendants knew and recklessly disregarded the fact the failure to properly package the polyethylene components of the Optetrak Device in vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) caused patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

353. Notwithstanding the foregoing, Defendants aggressively marketed the Optetrak Devices without disclosing the aforesaid side effects or changing the packaging to include vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH).

354. Defendants knew of the Optetrak Device's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm.

355. Defendants' intentional and/or reckless fraudulent and malicious failure to disclose information deprived the Plaintiff and his surgeon of necessary information to enable them to weigh the true risks of using the Optetrak Devices against its benefits.

356. The aforesaid conduct of the Defendants was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

357. Defendants' actions showed willful misconduct, malice, fraud, wantonness,

oppression or that the entire want of care raises the presumption of conscious indifference to the consequences.

358. As a direct and proximate result of the Defendant's conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries as set forth above.

359. As a further direct, proximate and legal consequence of Defendants' acts and omissions, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a. Judgment in favor of Plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;

b. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

c. Punitive and/or exemplary damages in such amounts as may be proven at trial;

d. Attorneys' fees and costs;

e. Interest; and

f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Dated: March 13, 2023

Respectfully submitted,

By: *s/Ellen Relkin, Esq.*

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DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury.

Dated: March 13, 2023

Respectfully submitted,

By: *s/Ellen Relkin, Esq.*

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